K961025

APR 15 1996

Premarket Notification

510(k) Summary of Safety and Effectiveness Information

DATE OF SUMMARY PREPARATION

March 5, 1996

MANUFACTURER

MedicineLodge, Incorporated
152 South 600 West
Logan, Utah 84321
Telephone: (801) 753-7675
Fax: (801) 753-7698

MANUFACTURER CONTACT PERSON

Alan Chervitz, President
MedicineLodge, Inc.
152 South 600 West
Logan, Utah 84321
Telephone: (801) 753-7675
Fax: (801) 753-7698

REGULATORY CORRESPONDENCE

Correspondence related to this submission may be addressed to:

Brian T. Cleary
Director of RA/QA
Hayes Medical, Inc.
819 Striker Avenue, Suite 10
Sacramento, CA 95834-5432

Telephone: (916) 646-5441
Fax: (916) 646-5432

PROPRIETARY DEVICE NAME

EXPANDED BODY Suture

COMMON NAME

Braided Nonabsorbable Polyester Surgical Suture

CLASSIFICATION NAME

Nonabsorbable Poly(ethylene terephthalate) Surgical Suture

CLASSIFICATION REFERENCE

21 CFR § 878.5000

DEVICE PRODUCT CODE

79 GAT

REGULATORY CLASS

In accordance with FDA classification of nonabsorbable synthetic poly(ethylene terepthalate) sutures as Class II medical devices, this device is proposed for placement in Class II.

SPECIAL CONTROLS

At this time, Food and Drug Administration generated Performance Standards applicable to the **EXPANDED BODY** suture are not in force. In accordance with 21 CFR § 878.5000, testing has been performed confirming that the **EXPANDED BODY** suture meets applicable United States Pharmacopiea (USP) requirements as described in the USP Monograph for Nonabsorbable Surgical Suture, with the exception of suture diameter.

USP COMPLIANCE TESTING

As required by 21 CFR § 878.5000, device testing has been conducted to verify that the **EXPANDED BODY** suture meets all applicable USP standards for nonabsorbable surgical sutures, with the exception of suture diameter. MedicineLodge, Inc. has conducted the following tests on a representative USP #5 **EXPANDED BODY** suture to verify conformance with the USP standards listed below.

1) Suture Needle Attachment Testing (USP # 871)
2) Suture Tensile (Knot Pull) Test (USP # 881)

Results from these tests confirm that the USP #5 **EXPANDED BODY** suture exceeds applicable requirements for USP tests #871 and #881 for nonabsorbable surgical sutures. MedicineLodge, Inc. believes that the results of this testing are representative of the performance of all USP sizes of this device and demonstrate that all USP size **EXPANDED BODY** sutures will exceed these requirements.

MATERIALS

The following materials are used in the manufacture of the **EXPANDED BODY** suture.

Poly(ethylene terepthalate): in accordance with 21 CFR § 878.5000, the **EXPANDED BODY** suture is constructed of poly(ethylene terepthalate). This material is similarly used in the manufacture of the all predicate devices and its clinical use is therefore well established. The expanded midsection of the device is similarly comprised of this material.

Color Additives: the **EXPANDED BODY** suture will be colored using the following coloring additives:

- D&C Blue #6
- D&C Green #6
- White (Standard/Undyed)

D&C Blue #6 and D&C Green #6 are similarly used to dye all predicate devices. FDA has indicated that these colors are approved for the dying of polyester sutures.

Stainless Steel: the needle portion of the **EXPANDED BODY** suture is manufactured from 420C Stainless Steel (ASTM F-899).

INDICATIONS FOR USE

The **EXPANDED BODY** suture is indicated for use in soft-tissue approximation and/or ligation in rotator cuff repair procedures.

DEVICE DESCRIPTION

The **EXPANDED BODY** suture is a braided, nonabsorbable, sterile, surgical suture composed of Poly(ethylene terapthalate) intended for use in rotator cuff soft-tissue repair procedures. This device is prepared from fibers of high molecular weight, long-chain, linear polyesters having recurrent aromatic rings as an integral component.

The **EXPANDED BODY** suture is identical to currently marketed polyester sutures within this device class with the exception of the following:

1) a new labeled indication for use stating specific use in rotator cuff soft tissue repair procedures, and
2) a new design which incorporates an expanded midsection equidistant from both ends of the suture possessing a larger outer diameter (two to four times) than the standard USP size.

The outer diameter of the expanded midsection thus has a cross-sectional area equal to or greater than the cross-sectional area of the needle or drill used to create the hole in the tissue. This ensures that the expanded midsection firmly engages the hole created by the drill or needle in the tissue. The rationale behind this new design is discussed in detail on the following page.

MedicineLodge, Inc. plans to provide the **EXPANDED BODY** suture in USP sizes #0 through #5 (metric sizes 3.5 through 7). All sutures will be 30 inches in length, available in 5 different colors (undyed white, dyed green, dyed blue, and white/blue and white/green combinations), and provided with and without attached needles.

For all **EXPANDED BODY** sutures, the length of the expanded midsection of the device will range from 15 mm to 25 mm and the diameter of the expanded midsection will range from two to four times the diameter of the corresponding USP size of the suture. All device labeling will specify exact expanded midsection dimensions for each USP size.

SUBSTANTIALLY EQUIVALENT PREDICATE DEVICES

MedicineLodge, Inc. believes that several commercially available devices are substantially equivalent to the **EXPANDED BODY** suture. Within the proposed class, the following devices were used as predicate devices for comparison in establishing the substantial equivalence of the **EXPANDED BODY** suture:

1) **TI•CRON - Nonabsorbable Polyester Surgical Suture**
Davis + Geck, Manati, PR; Danbury, CT

2) **POLYVIOLENE - Nonabsorbable Polyester Surgical Suture**
Look, Inc., Norwell, MA

SUBSTANTIAL EQUIVALENCE COMPARISON

To begin, the materials, method of manufacture, method of sterilization, and device packaging are identical to predicate devices. Additionally, as with all predicate devices, the **EXPANDED BODY** suture meets all USP requirements applicable to nonabsorbable sutures, with the exception of suture diameter.

As indicated previously, the only differences that distinguish the **EXPANDED BODY** suture from the selected predicate devices are:

1) a new labeled indication for use stating specific use in rotator cuff soft tissue repair procedures, and
2) a new design which incorporates an expanded midsection possessing a larger outer diameter (two to four times) than the standard USP size.

Devices that have previously received 510(k) clearance within 21 CFR § 878.5000 are specifically indicated for use in all types of soft tissue repair, including specific stated use in cardiovascular, opthalmic and neurological procedures. Unlike the proposed labeling for the **EXPANDED BODY** suture, the predicate devices do not specify a labeled indication for use in orthopedic soft-tissue repair.

However, it should be mentioned that all predicate device labeling states *no known* contraindications. It is our understanding that suture devices are used regularly in orthopedic soft tissue approximation and/or ligation.

Medical literature documents the widespread use of nonabsorbable polyester suture devices for soft-tissue repair of the shoulder, including rotator cuff repair. Hence, although the labeled indication for use of the **EXPANDED BODY** suture is new, the practice of using nonabsorbable, polyester suture devices for the same indication is well documented in medical literature.

Design Difference - Expanded Midsection

The rationale behind the expanded midsection design is to increase the outer diameter of the suture to more firmly engage and fit the hole created by the needle or drill in the bone tissue during suture insertion. This increased outer diameter also results in an increased suture surface area contained in the formed hole.

This larger surface area potentially reduces the chances of suture or bone failure by more evenly distributing any applied force to the surrounding bone tissue. The expanded midsection feature more evenly distributes the applied force over the bone surface, the **EXPANDED BODY** suture potentially increases the maximum pull-out strength of the suture relative to standard, similarly sized polyester sutures.

A representative USP #5 **EXPANDED BODY** design configuration was used for all comparative testing. This design combines dimensions for the expanded midsection that fall at the lower end of the design limits for a USP #5 **EXPANDED BODY** suture - lower-end design limit length (16.5 mm) and less than minimum outer diameter ($1.27 \text{ mm} < 2x = 1.499 \text{ mm}$). The predicate device used for comparison was a USP #5 **TI•CRON** (Davis + Geck) nonabsorbable, polyester suture.

Comparative testing was performed using *Last-a-Foam* Polyurethane Foam as a simulated bone material. Use of this material for comparative device testing assures that the **EXPANDED BODY** and **TI•CRON** suture samples are tested in a uniform material so that variation of material properties is controlled. In this way, the results of the test measure only the difference in performance of the two suture types.

The test results confirm that the **EXPANDED BODY** suture performs equivalent to the **TI•CRON** suture in this simulated application.

Conclusion

Based on the design concept, use of standard materials, feature comparisons to the selected predicate devices, and device testing, MedicineLodge, Inc. believes that sufficient evidence exists to conclude that the **EXPANDED BODY** suture is substantially equivalent to existing legally marketed nonabsorbable polyester suture devices.

Additionally, the information presented herein should support our request for labeled "indications for use" in soft-tissue approximation and/or ligation in rotator cuff repair procedures.

Table 1 on the following page summarizes the relevant feature comparisons between the **EXPANDED BODY** suture and the selected predicate devices.

TABLE 1

Feature comparisons between the **EXPANDED BODY** suture and **Ti•Cron** (Davis + Geck) and **Polyviolene** (Look, Inc.) predicate devices (differences are indicated in **bold** print)

	EXPANDED BODY Polyester Nonabsorbable Surgical Suture, USP	**TI•CRON** Polyester Nonabsorbable Surgical Suture, USP	**POLYVIOLENE** Polyester Nonabsorbable Surgical Suture, USP
Indications	**Soft-tissue approximation and/or ligation in rotator cuff repair procedures.**	**General soft tissue approximation and/or ligation, including use in cardiovascular, opthalmic and neurological procedures.**	**General soft tissue approximation and/or ligation, including use in cardiovascular, opthalmic and neurological procedures.**
Contraindications	None known	None known	None known
Materials	Poly(ethylene terepthalate)	Poly(ethylene terepthalate)	Poly(ethylene terepthalate)
Expanded Midsection	**Length: 15 mm to 25 mm Outer Diameter: 2 to 4 times the corresponding USP size**	**No**	**No**
Sterilization	Gamma	Gamma	Gamma
Pledgets	No	Yes (PTFE)	Yes (PTFE)
Needles	With and without	With and without	With and without
Sizes	USP 0 through 5	USP #7-0 through #5	USP #11-0 through #5
Colors	Blue, Green, White; Blue/White and Green/White combinations	Blue and White	Green and White
Manufacturer	MedicineLodge, Inc.	Davis + Geck	Look, Inc.
510(k) Approved	N/A	Yes	Yes